UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,979	04/07/2006	Shigeru Chikase	2006-0391A	8777

513 7590 03/13/2008

WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
03/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,979	CHIKASE ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 -11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/7/06; 2/9/07; 8/30/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1 – 11 are pending and are currently under examination.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1 – 5, 7 and 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4 – 9 and 12 of copending Application No. 10/530,046. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite compositions comprising cefditoren pivoxil, a sugar ester fatty acid and the optional presence of a water soluble polymer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112 1st Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1 – 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amount of the various ingredients present in the compositions is related to the efficacy of 100 mg of the drug cefditoren pivoxil. No indication is given in the specification as to how one determines the efficacy of 100 mg of cefditoren pivoxil (e.g., a certain solubility in water or buffer, bioabsorption in a subject administered the solid composition or the ability kill a certain percentage of a bacterial strain) so that one known the basis on which the amount of other ingredients present is computed.

Claim Rejections - 35 USC § 112 2nd Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1 – 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The independent claim requires at least 0.1 mg of a sugar ester fatty acid in a solid dispersion composition. The claim then states "on the

basis of an amount equivalent to 100 mg efficacy of cefditoren pivoxil." One interpretation is that the sugar ester fatty acid (and the water-soluble polymer) are able to exert an effect that is equivalent to that of cefditoren pivoxil. A basis could also be used in a ratio such as weight percent, but all of the amounts of ingredients claimed are absolute masses of each component and are not weight ratios. Therefore, if the cefditoren pivoxil need be present in the composition and the amounts of the other ingredients cannot be determined, rendering the metes and bounds of the claims indefinite.

For the purposes of applying art, the claims have been interpreted to require the presence of both the claimed amount of sugar ester fatty acid, cefditoren pivoxil and where appropriate, a pharmaceutically acceptable water-soluble polymer.

7. Claims 1, 2, 4, 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by

such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation of at least 0.1 mg of a sugar ester fatty acid, and the claim also recites at least 5 mg of a sugar ester fatty acid which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1, 2 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over the English abstract of JP 60132918 (JP'918, cited on PTO-1449, a full copy of the Japanese patent is also enclosed) in view of the Merck Index entry for cefditoren.

JP'918 discloses compositions comprising a cephalosporin antibiotic and a sucrose fatty acid ester (ln 1 – 2) which had improved oral absorbability (ln 10 – 11). Sucrose fatty acid ester is an example of a sugar ester fatty acid. These compositions can be administered in solid dosage forms such as granule, capsules or tablets (ln 14 – 15). The amount of the sucrose fatty acid ester present in these compositions is between 0.01 and 50% by weight when compared to that of the cephalosporin antibiotic.

JP'918 does not disclose the amount of these ingredients by absolute weight and does not exemplify cefditoren pivoxil as a cephalosporin antibiotic.

Cefditoren is a third generation cephalosporin and the active metabolite of the pivaloyloxymethyl ester prodrug known as cefditoren pivoxil (Merck Index entry).

Cefditoren pivoxil is a functional equivalent to the cephalosporins disclosed in JP'218. If one formulated a composition with 100 mg of cefditoren pivoxil, based on the weight ratios disclosed in JP'918, the compositions would contain between 0.01 and 50 mg of sucrose fatty acid ester. Thus, the composition of claims 1 and 2 is disclosed in the prior art when the weight ratios is used to calculate absolute amounts of the ingredients.

How long the cefditoren pivoxil is maintained in an amorphous sate when suspended in water as in claim 8 is not disclosed in the prior art. It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Therefore the claims of the instant application would have been obvious to one of ordinary skill in the art at the time of the instant invention.

12. Claims 1, 3 – 7 and 9 – 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kikkoji et al. (EP0629494, cited on PTO-1449) in view of the English abstract of JP 60132918.

Kikkoji et al. discloses pharmaceutical compositions for oral administration of cefditoren pivoxil and hydroxypropylcellulose (p 2, ln 3 – 4), a pharmaceutically

acceptable water-soluble polymer. While addition of (pivaloyl)oxy methyl group to cefditoren (resulting in cefditoren pivoxil) increases the fat solubility of the drug and improved absorption in the gastrointestinal tract (p 2, ln 10 – 17), it also decrease water wettability, dispersilbility and solubility (p 2, ln 17 – 19). Because of these differing effects, a net increase in absorption of the drug is not always realized. This problem is solved and the absorption of the drug is improved without a concomitant increase in the bitterness of the pharmaceutical by combining cefditoren pivoxil with the water soluble high polymer hydroxypropylcellulose (p 2, ln 36 – 40). The amount of the polymer is 0.4 or more weight parts to one weight part of cefditoren pivoxil (p 2, ln 57 – p 3, ln 5).

These compositions can further comprise a variety of pharmaceutical excipients such as disintegrating agents, binders, fillers, sweeteners, perfumes, and lubricants (p 3, ln 11 – 16). The pharmaceutical compositions are intended for oral administration whose dosage forms includes capsules, granules, powders and tablets (p 3, ln 17 – 18).

The amount of cefditoren pivoxil in the tablets or capsules is 50 – 200 mg provided that 100 mg potency corresponds to about 130 mg weight of cefditoren pivoxil (p 3, ln 27 – 29). In the examples, 130 mg corresponds to an efficacy of 100 mg of cefditoren pivoxil. In example 1, a composition comprising 130 mg of cefditoren pivoxil and 260 mg of hydroxypropylcellulose, a ratio of hydroxypropylcellulose to cefditoren pivoxil is prepared (p 3, ln 38 – 50). Powder preparations with ratios of hydroxypropylcellulose to cefditoren pivoxil as high as 4.0 were also prepared. A composition of that ratio would contain 130 mg of cefditoren pivoxil and 32.5 mg of hydroxypropylcellulose.

Kikkoji et al. does not teach the inclusion of sugar fatty acid ester (sugar ester fatty acid) nor a liquid composition in which the solid composition is dissolved or suspended in a liquid.

JP'918 discloses compositions comprising a cephalosporin antibiotic with the sucrose fatty acid ester (ln 1 – 2) which had improved oral absorbability (ln 10 – 11). These compositions can be administered in solid dosage form such as granules, capsules or tablets (ln 14 – 15) but also when dissolved or suspended in a medium such as water or phosphoric acid buffer solution (ln 11 – 14). The amount of the sucrose fatty acid ester present in these compositions is between 0.01 and 50 % by weight when compared to that of the cephalosporin antibiotic.

For the compositions exemplified in Kikkoji et al. above with 130 mg of cefditoren pivoxil would mean that the composition could contain between 0.013 and 65 mg of sucrose fatty acid ester.

Since both Kikkoji et al. and JP'918 disclose compositions of the specific cephalosporin antibiotic cefditoren pivoxil or cephalosporin antibiotics in general that improve the oral absorbability of the drug, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine them. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) **MPEP 2144.06**. In this instance, the purpose is increasing the

oral absorbability of the drug. The resulting composition comprises cefditoren pivoxil, a sucrose fatty acid ester and a water-soluble polymer in the amounts claimed by Applicant, thus rendering the claims of the instant application obvious.

Conclusion

Claims 1 – 11 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW